

EXHIBIT M

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April 18, 2024

Conor Lamb, Esquire
Kline & Specter, PC
1525 Locust Street, 19th Floor
Philadelphia, PA 19102

Re: Wolking v. Lindner MD, and Youngs Apothecary, Inc. d/b/a Tunkhannock Compounding Center

Dear Mr. Lamb:

I am a Pharmacist licensed in the state of Florida since 1992. My current position is Associate Vice President, Operations at University of Florida Health. I serve as the hospital leader with oversight of clinical departments including Pharmacy Services. I also hold an academic appointment as a Clinical Associate Professor in the Department of Pharmaceutical Outcomes and Policy at the University of Florida College of Pharmacy. I have served as the President of the Florida Society of Health-System Pharmacists. Over the course of my career, I have authored many articles in peer-reviewed medical literature and given numerous national and international presentations. Please consider the attached Curriculum Vitae to be incorporated into this report. My fees for serving as an expert are as follows: \$375/hour for records review and \$500/hour for deposition and trial testimony.

Factual Background

The following documents and records have been reviewed in preparation of this report:

1. Complaint
2. Lindner Chart 1-607.pdf
3. Pharmacy records provided by Stacey Wolking (P4-000001-07)
4. Wolking pill bottle images (P3-000001-04)
5. Courtney Young PharmD deposition transcript with exhibits
6. Brian Bryk PharmD deposition transcript with exhibits
7. Dr. Henry Lindner MD deposition transcript with exhibits
8. Tunkhannock Compounding Center 30(b)(6) deposition transcript with exhibits
9. The opinion of the Pennsylvania Superior Court in *Riff v. Morgan Pharmacy*

Stacy Wolking sought out medical care from Henry Lindner, MD at HormoneRestoration.com and completed a medical history form on November 1, 2013. She was 51 years old. Her address was listed as Purcellville, Virginia. Ms. Wolking listed her medical condition as "biotoxin illness/post-lyme." She listed her current hormone treatments as E3, E2, Prog (100) Troche, and 12.5mg DHEA troche. Her treatment goals included no hot flashes, HRT that was safe, and less

periods. Ms. Wolking indicated her symptoms included fatigue, aches and pains, cold hands and feet, weight gain, depression, dry skin, mental slowness, sugar cravings, irregular periods, hot flashes, night sweats and moodiness. Ms. Wolking received medical care from Dr. Lindner from 2013 through 2022. The following represents each diagnosis included in Ms. Wolking's formal health record at the office of Dr. Lindner.

11/1/2013	Fatigue/Malaise
11/1/2013	Menopausal State, Symptomatic
11/1/2013	Vitamin D Deficiency
3/10/2015	Glucocorticoid Deficiency
11/19/2015	Glucocorticoid Deficiency
11/19/2015	Menopausal State, Symptomatic
11/19/2015	Vitamin D Deficiency
5/9/2017	Iron Deficiency Unspecified
5/24/2018	Fatigue/Lethargy
1/17/2022	Babesiosis due to Babesia Odocoilei

Dr. Lindner eventually prescribed Ms. Wolking extremely high doses of corticosteroids, including prednisone, hydrocortisone, and dexamethasone. The following pharmacies dispensed Dr. Lindner's corticosteroid prescriptions to Ms. Wolking: Harris Teeter, Wal-Mart, and Tunkhannock Compounding Center. In an email dated August 15, 2022, Dr. Lindner directed Ms. Wolking to obtain certain high-dose corticosteroid prescriptions from Tunkhannock Compounding Center because her local pharmacy (Harris Teeter) might complain to his medical board about the high doses.

The Complaint alleges that Tunkhannock Compounding Center dispensed four prescriptions for high doses of corticosteroids.¹ These occurred on August 8, August 16, September 27 and October 5, 2022.

August 8	Rx 155694	Prednisone 10mg tablets, #500, 30 day supply <i>Instructions: Up to 10 tabs po daily as directed</i>
August 16	Rx 155853	Dexamethasone 4mg tablets, #200, 50 day supply <i>Instructions: Take up to 4 tabs po daily in divided doses as directed</i>
September 27	Rx 156272	Dexamethasone 4mg, #100, 50 day supply <i>Instructions: Take up to 10 tabs po daily as directed</i>
October 5	Rx 156272	Dexamethasone 4mg, #100, 50 day supply <i>Instructions: Take up to 10 tabs po daily as directed</i>

Courtney Young, PharmD was the owner and pharmacist in charge at Tunkhannock Compounding Center in 2022 at the time of the corticosteroid dispenses to Ms. Wolking. Tunkhannock Compounding Center is located in the same building as Dr. Lindner's medical practice in Tunkhannock, Pennsylvania. Pharmacist Young would ask Dr. Lindner questions

¹ On P4-000003, there is evidence of a prednisone prescription for Ms. Wolking from TCC on 5/19/22.

about his patients. She states she had conversations with Dr. Lindner about corticosteroids, but not specifically about safe doses. She never asked him how much prednisone or dexamethasone would be safe for one of his patients.

Pharmacist Young testified that she has had conversations with Dr. Lindner about how sick his patients are from babesiosis. (Nov. 15, 2023 Young Dep. At 56-57.) She was aware in August 2022 that Ms. Wolking received a treatment plan from Dr. Lindner related to the diagnosis of babesiosis and the use of corticosteroids. (*Id.* at 57-58.) During Pharmacist Young's deposition, she testified that she had a conversation with Dr. Lindner about Ms. Wolking before Tunkhannock Compounding Center dispensed the August 8, 2022 corticosteroid prescription (*Id.* at 74-76) and that she had an understanding with Dr. Lindner that Ms. Wolking would use patient-directed dosing. (*Id.* at 85-86.) Pharmacist Young testified that she does not know whether she actually initiated the conversation with Dr. Lindner, nor does she remember the date or many of the details of the conversation. (*Id.*) Yet she acknowledged in her deposition that this was possibly the largest prednisone prescription she had ever dispensed. (*Id.* at 78-79.)

Pharmacist Young stated she was satisfied with the explanation provided by Dr. Lindner concerning the prescriptions for Ms. Wolking and felt it was reasonable to fill the prescriptions with doctor approval. (*Id.* at 88-89.) Even though she and Dr. Lindner did not discuss potential negative side effects and risks of such high corticosteroid doses, she testified in her deposition that she believed it was reasonable to dispense the August 8, 2022 prescription. (*Id.* at 80, 89.) Pharmacist Young also testified that she doesn't believe it's possible to overdose on prednisone. (*Id.* at 22-23.)

Pharmacist Young testified that she does not remember ever having a second conversation with Dr. Lindner about Ms. Wolking, even as the dosages of her corticosteroid prescriptions grew in August and September 2022, and even as Pharmacist Young recognized that they were therapeutically duplicative. (*Id.* at 97-100.) Pharmacy Young spoke to Pharmacist Byrk because the prescriptions were not something they would normally fill. (*Id.* at 86.)

On August 16, Pharmacist Young personally dispensed Rx 155853 for dexamethasone to Ms. Wolking. She acknowledged the therapeutic duplication between prednisone and dexamethasone, but stated her belief that prednisone had been discontinued. (*Id.* at 98.) Pharmacist Young was unable to provide any documentation to support this belief. She also testified that this was possibly the largest dexamethasone prescription she had ever dispensed. (*Id.* at 101.)

Pharmacist Young testified she was aware of the Pharmacist requirement to perform prospective drug review or PDR for each prescription dispensed. (*Id.* at 30-31.) Title 49 Pa. Code 27.19 requires a Pharmacist to conduct prospective drug review and patient counseling in the process of dispensing prescription medications. The Pharmacist is required to evaluate the prescription to identify potential drug therapy problems that might result from therapeutic duplication, drug-drug interactions, incorrect dosage, incorrect duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

Pharmacist Bryk was employed by Tunkhannock Compounding Center and was personally responsible for dispensing the corticosteroid prescriptions referenced above on August 8, September 27 and October 5. (Feb. 2, 2024 Bryk Dep. at 7, 14-15; Ex. 1.) He had a duty,

independent of Pharmacist Young, to conduct a PDR for each of the prescription corticosteroid dispenses. Pharmacist Bryk could have used a variety of drug information resources to validate the starting dose of corticosteroids. It's often necessary go beyond the FDA approved product labeling while conducting drug information research, yet Pharmacist Bryk could not think of any reference material that he uses besides the package insert, or a bookmarked website or web search. (*Id.* at 28-29.) It's clear Pharmacist Bryk did not have a complete understanding of corticosteroid dosing. He even testified that he did not know if it's possible to overdose on prednisone or dexamethasone. (*Id.* at 40-41.)

Pharmacist Bryk testified that he did not remember whether he knew the diagnosis of Ms. Wolking. (*Id.* at 8-10.) He was aware Ms. Wolking was a patient of Dr. Lindner. (*Id.* at 11.) Pharmacist Bryk does not recall ever speaking with Pharmacist Young or Dr. Lindner about the corticosteroid prescriptions prior to dispensing to Ms. Wolking. (*Id.* at 12-16.) When questioned about a situation in which he has questioned a prescribing physician, Pharmacist Bryk responded with "when you think something is out of the realm of normalcy." (*Id.* at 22.)

Pharmacist Bryk described situations where he believes prednisone and dexamethasone are not necessarily therapeutically duplicative. (*Id.* at 38-40.) While each of the stated situations may be legitimate, he made no independent effort to resolve this real conflict by either discussing with Ms. Wolking or Dr. Lindner.

Dr. Lindner does not represent himself as an endocrinologist or consider himself an infectious disease physician. (Feb. 21, 2024 Lindner Dep. at 21-22.) His medical practice centers on hormone replacement therapies (HRT). (*Id.*) Dr. Lindner sends prescriptions to Tunkhannock Compounding Center due to their specialization in this area of pharmacy practice. (*Id.* at 281-82.) Dr. Lindner diagnosed his daughter with chronic babesiosis, a medical diagnosis he states he invented, and discussed the "disease" and treatment directly with Pharmacist Young and Pharmacist Bryk on multiple occasions. (*Id.* at 62-63, 286-88, 295.) Dr. Lindner also stated Pharmacist Young never asked for any reference materials or documents. (*Id.* at 289.) Dr. Lindner testified Pharmacist Young understood his practice and why he wanted the person to have large amounts of steroids on hand, in case they needed very high amounts for some period of time, as he had discussed with my daughter. And he had bought it in the same way for his daughter. He would buy several bottles of prednisone or dexamethasone at once. (*Id.* at 305.)

Dr. Lindner stated chronic babesiosis is not a medical diagnosis recognized by the Infectious Disease Society of America (IDSA) or the Centers for Disease Control (CDC). (*Id.* at 63-64.) In fact, he referred to these international medical experts as "ignorant." (*Id.* at 132.) Pharmacist Young also testified that the CDC was "not on the cutting edge of information."

Dr. Lindner believes there is no upper limit to corticosteroid dosing. This corticosteroid treatment approach lacks scientific merit or published evidence to support. No reasonable Pharmacist would dispense these corticosteroid prescriptions to Ms. Wolking. Dr. Lindner stated he never discussed the treatment plan for Ms. Wolking with either Pharmacist Young or Pharmacist Bryk. He described the drugs Ms. Wolking received from TCC as "a mountain of steroids." (*Id.* at 307.)

Prednisone and dexamethasone belong to the corticosteroid class of medications. They are mainly prescribed for their anti-inflammatory effects in different disorders or many organ

systems. Corticosteroids cause profound and varied metabolic effects, modifications to the immune response of the body to diverse stimuli and are used as replacement therapy for adrenocortical deficient patients.

According to the online drug reference, Micromedex, the initial adult dosage for prednisone should not exceed 60-80mg/day for non-cancer indications. The official, FDA-approved, product label for prednisone includes a section for Dosage and Administration. As described in the product labeling, the initial dose of prednisone may vary from 5mg – 60mg per day depending on the specific disease entity being treated. The dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient. The lowest effective dose should be prescribed. Prednisone 5mg is approximately equal to dexamethasone 0.75mg, which closely tracks Dr. Lindner's preferred conversion of 7:1 between prednisone and dexamethasone.

Ms. Wolking was dispensed prednisone up to 100mg/day and dexamethasone up to 40mg/day (equivalent to approximately 266 mg/day prednisone). Corticosteroids can cause extremely serious adverse effects when administered in excessive amounts and/or over long duration of treatment. Organ systems impacted include cardiovascular, endocrine, gastrointestinal, immunologic, musculoskeletal, ophthalmic, psychiatric, and respiratory. Pharmacist Young and Pharmacist Bryk should have initiated contact with Dr. Lindner to determine the legitimacy of these prescriptions based on several factors, including the initial dosage exceeding the FDA approved product labeling and other drug information resources, and prescription instructions stating take "up to" a specified amount, which implies the actual daily dose may be at the discretion of the patient. In addition, it's clear from deposition testimony that Pharmacist Young and Pharmacist Bryk had prior knowledge that Dr. Lindner allowed his patients taking high-dose corticosteroid to self-titrate daily dosages, which should have raised serious concern about this prescribing practice.

Ms. Wolking developed very serious and potentially fatal adverse reactions. Her adverse effects included the painful perforation of her bowel, severe steroid myopathy, pounding heart, high heart rate, puffy face, weight gain, and severe diarrhea. Ms. Wolking's husband described her as near comatose. Dr. Lindner acknowledged the excessive dosages of corticosteroids were weakening her muscles, bones and connective tissue. Following months of extremely high doses of corticosteroids, Ms. Wolking was hospitalized in October 2022 with a small bowel perforation and peritonitis. In the hospital, Ms. Wolking refused nutrition and medical treatment and demanded to be transferred to hospice care and allowed to die.

Opinions:

1. Duty: Pharmacists in Pennsylvania have a duty to exercise due care and diligence in the performance of their professional duties, including a duty to warn a patient or notify a prescribing physician when a prescription is unreasonable on its face, creating a substantial risk of serious harm to the patient.² Because the initial dosage exceeded the official, FDA-approved, product label and other reputable drug information resources,

² See *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1251-52 (Pa. Super. Ct. 1986).

Pharmacists Courtney Young and Brian Bryk had a duty to contact Dr. Lindner to ensure the appropriateness of the prescription.

2. Breach: Pharmacists Courtney Young and Brian Bryk breached their duty and fell below the standard of care by dispensing prednisone and dexamethasone prescriptions in excessive doses to Ms. Wolking from August to October 2022. In just eight days in August 2022, Tunkhannock Compounding Center (acting through Brian Bryk and Courtney Young) dispensed the equivalent of 10,600 mg of prednisone to Stacey Wolking, a single patient who was not hospitalized. Neither pharmacist warned Ms. Wolking about the substantial risk of serious harm presented by this quantity of corticosteroids, nor did they notify Dr. Lindner that these prescriptions were facially unreasonable. In this case, although Pharmacist Young claims that she spoke to Dr. Lindner about Ms. Wolking before the August 8, 2022 prescription, she testified that she does not know whether she even initiated her conversation with Dr. Lindner, and she did not discuss negative side effects or risks with him. Dr. Lindner did not recall talking to Pharmacist Young about Ms. Wolking at all. There is no evidence that Brian Bryk ever spoke to Dr. Lindner about Ms. Wolking. Thus, the evidence is conflicting concerning whether either Tunkhannock Compounding Center ever performed the required inquiry of Dr. Lindner about these prescriptions. Because of the extremely high and potentially fatal corticosteroid doses involved, the standard of care required both Pharmacists to go beyond the traditional inquiry to the prescribing physician and conduct an independent investigation into the appropriateness of dispensing corticosteroids to Ms. Wolking. Both Pharmacists should have known the significant health risk posed by the extremely high corticosteroid doses. The normal doses for corticosteroids are listed in common reference materials and easy for any pharmacist to find.
3. Cause: Tunkhannock Compounding Center caused Ms. Wolking's injuries because it was the only pharmacy Lindner could rely on to prescribe such large and dangerous corticosteroid doses. Dr. Lindner testified other pharmacies would likely not have filled these large prescriptions. (*Id.* at 305.) Pharmacist Young testified that Ms. Wolking's prescriptions were larger than what she saw when she worked at Rite-Aid, and Lindner instructed Ms. Wolking to fill her prescriptions at Tunkhannock Compounding Center because he believed more mainstream pharmacies would question or refuse to fill such large prescriptions, and even report him to his medical board. Although Ms. Wolking still filled some smaller corticosteroid prescriptions at Harris Teeter in August 2022, a careful review of her emails with Dr. Lindner and his medical chart makes clear that the vast majority of corticosteroids she consumed in August, September, and October 2022 were dispensed by Tunkhannock Compounding Center. That pharmacy's failure to exercise the same caution toward Dr. Lindner as the mainstream pharmacies caused the unsafe doses of corticosteroids to reach Ms. Wolking and inflict the injuries described in the Complaint. Based on my experience, no mainstream pharmacy would have dispensed these prescriptions without questioning Dr. Lindner.

I reserve the right to amend these opinions if more information becomes available.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Th Johns".

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Associate Vice President, Operations
University of Florida Health
Clinical Associate Professor
Department of Pharmaceutical Outcomes and Policy
University of Florida College of Pharmacy

Curriculum Vitae

Thomas Johns, PharmD

Personal Information

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Home Address: 5902 NW 72nd Street
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Licensure: Florida (Pharmacist) PS 28039
Florida (Consultant Pharmacist) PU 5721

Education and Training

1992-1993 Adult Internal Medicine Pharmacy Practice Residency
VA Medical Center/ University of Florida College of Pharmacy
Gainesville, Florida

1987-1992 Doctor of Pharmacy
University of Florida College of Pharmacy
Gainesville, Florida

Professional Experience

Apr 2021-Present Associate Vice President, Operations
UF Health Shands Hospital, Gainesville, Florida

Serve as hospital leader with oversight of clinical departments including Pharmacy, Radiology, Radiation Oncology, Ambulatory Infusion Center, and Cancer Registry.

- Responsible for greater than 900 employees.
- Administer annual budget of \$253M in total operating expense.
- Pharmacy areas include inpatient operations across three patient care towers, four outpatient pharmacies, ambulatory infusion center pharmacy, offsite supply chain distribution and 340B program compliance.

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Aug 2020-Apr 2021	Executive Director, Operations/Pharmacy UF Health Shands Hospital, Gainesville, Florida
Apr 2018-Aug 2020	Director, Pharmacy and Operations UF Health Shands Hospital, Gainesville, Florida
Mar 2014-Apr 2018	Director, Pharmacy Services UF Health Shands Hospital, Gainesville, Florida
Mar 2013-Mar 2014	Interim Director, Pharmacy Services UF Health Shands Hospital, Gainesville, Florida
Apr 1999-Mar 2013	Assistant Director, Pharmacy Services Shands at the University of Florida, Gainesville, Florida
Jul 1994-Apr 1999	Clinical Pharmacist, Adult Internal Medicine/Infectious Diseases Shands at the University of Florida, Gainesville, Florida
Aug 1993-Jul 1994	Clinical Pharmacist, Adult Internal Medicine Florida Hospital Medical Center, Orlando, Florida
Jul 1983-Jan 2001	US Army/Army Reserve Pharmacy Technician 1983-1993 Persian Gulf War Veteran 1990-1991 Pharmacist 1993-2001

Academic Appointments

Feb 2013-Present	Clinical Associate Professor Department of Pharmaceutical Outcomes and Policy University of Florida College of Pharmacy, Gainesville, Florida
Sept 1992-Feb 2013	Clinical Assistant Professor University of Florida College of Pharmacy, Gainesville, Florida

Publications

Winterstein AG, Staley B, Henrickson C, Xu Dandan, Lipori G, Jeon N, Choi Y, Li Y, Castillo JH, Soria-Saucedo R, Brumback B, **Johns TE**. Development and validation of a complexity-score to rank hospitalized patients at risk for preventable adverse drug events. *Am J Health-Syst Pharm* 2017;74(23):1970-1984.

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Johns TE, Harbilas JW. Drug-Induced Hematologic Disorders. In: DiPiro JT, Talbert RL, Yee GC, et al, eds. *Pharmacotherapy: A Pathophysiologic Approach*. 4th ed. Stamford, CT: Appleton & Lange, 1999.

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Totleben ER, **Johns TE**, Orrick JJ, Klinker KP, Kahler DA and Kilroy RA. Design and Implementation of a Pharmacist Competency Assessment Program. 35th Annual American Society of Health-System Pharmacists Midyear Clinical Meeting. December 2000, Las Vegas, Nevada.

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Orrick J, Ramphal R, **Johns TE**, Russell WR. Improving antibiotic susceptibility of Type-1 beta-lactamase-producing organisms after formulary replacement of ceftazidime with cefepime. Abstract 731. 39th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). September 1999, San Francisco, California.

Johns TE, Hancock WW, Lopez LM. Does ibutilide cause ventricular tachycardia? Presented during the Annual Meeting of American College of Clinical Pharmacy. Phoenix, Arizona, November 1997.

Klinker KP, **Johns TE**, Lipowski E, and Lopez LM. Physician attitudes toward pharmacist-managed anticoagulation clinics. Presented during the Annual Meeting of American College of Clinical Pharmacy. Phoenix, Arizona, November 1997.

Johns TE, Spivey-Miller S, Lopez LM, Chen L, Mehta J. Celiprolol, but not felodipine, increases nitric oxide synthase activity and decreases superoxide anion generation in patients with hypertension. Presented as a platform presentation during the Annual Meeting of American College of Clinical Pharmacy. St. Louis, Missouri, August 1994.

Research and Project Experience

Winterstein AG, Lipori G, Johns TE, Belgado, B. Real-time risk stratification for hypo- or hyperglycemia to enhance glucose management outcomes in hospitals. Funded by the Food and Drug Administration (FDA), \$296,477. 2015.

Winterstein AG, Johns TE, Lipori G, Brumback B, Segal R. Development and Validation of a Complexity Score to Identify Hospitalized Patients at High-Risk for Preventable Adverse Drug Events. Funded by the American Society of Health-System Pharmacists Research and Education Foundation, \$500,000. 2013.

Patient Safety - Medication Error Prevention in Critical Access Hospitals. Florida Department of Health, Office of Rural Health/Florida Medical Quality Assurance, Inc., \$1,300,000. 2002-2015.

Health Information Technology (HIT) for Medication Safety in Critical Access Hospitals. Agency and Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services (DHHS), \$150,559. 2004-2005.

Identifying root causes of hyper- and hypoglycemic episodes for the development and implementation of intervention(s) to decrease their incidence. Funded by the American Society of Health-System Pharmacists Research and Education Foundation, \$1,900. 2002-2003.

Curriculum Vitae

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The nature and etiology of medication errors of omission - Creating an advanced knowledge base through solicited error reporting and systematic analysis. Funding provided by the Drug Information Association (DIA), \$25,000. 2002.

Development of a screening tool for medication errors in hospital inpatients. Funding provided by University of Florida Research and Graduate Programs, \$50,000. 2001-2002.

Development of a screening instrument for preventable drug-related morbidity in hospital inpatients. Funded by the American Society of Health-System Pharmacists Research and Education Foundation, \$22,900. 2001-2002.

Incidence and severity of antiretroviral drug interactions in a large teaching hospital. Merck, \$2,500. 1998-1999.

Professional Affiliations

American Society of Health-System Pharmacists

House of Delegates 2003, 2007, 2008, 2016

Florida Society of Health-System Pharmacists

President 2003-2004, 2015-2016

Interim Executive Vice President 2015-2016

Board of Directors 1999-2002

North Central Florida Society of Health-System Pharmacists

President 1997

Awards/Honors

Florida Society of Health-System Pharmacists Medication Safety Award	2008
Florida Society of Health-System Pharmacists Pharmacist of the Year	2005
Florida Society of Health-System Pharmacists Meritorious Service Award	2002, 2015
Florida Society of Health-System Pharmacists Forerunner Award	1997